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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,694	08/01/2003	Anthony Allison	SURR113	3876
25871	7590	03/25/2004	EXAMINER	
SWANSON & BRATSCHUN L.L.C. 1745 SHEA CENTER DRIVE SUITE 330 HIGHLANDS RANCH, CO 80129			SNEDDEN, SHERIDAN	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/632,694	<b>Applicant(s)</b> ALLISON, ANTHONY	
	<b>Examiner</b> Sheridan K Snedden	<b>Art Unit</b> 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 11-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.                                                |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10, drawn to a method of treating sickle-cell disease with an annexin protein coupled to at least one protein, classified in class 514, subclass 2.
  - II. Claims 11-15, drawn to a method of treating sickle-cell disease with an annexin protein coupled to PEG, classified in class 514, subclass 2.
2. The inventions are distinct, each from the other because of the following reasons:

The methods of inventions I and II require the use of patently distinct products that differ in structure and biological characteristics. Therefore, inventions I and II are patentably distinct.
3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Darla Yoerg on March 17, 2004 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Claim Objections***

Claim 10 is objected to because of the following informalities: The annexin V construct of SEQ ID NO: 6 was not found in the prior art and thus, claim 10 is allowable in independent form. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3, 4, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thorpe *et al.* (US 6,312,694) in view of Tait *et al.* (US 5,632,986), Stamatoyannopoulos (US 4,965,251), and Bertling *et al.* (DE 195 41 284 A1).

Thorpe *et al.* teach annexin V/antibody conjugates (the fc portion of the antibody) for use as an antithrombotic. SEQ ID NO: 3 is the amino acid sequence of annexin V. Thorpe *et al.* suggests the use of the annexin conjugates for the treatment of sickle cell anemia, by incorporating WO 97/17084 by reference and suggesting substituting the Annexin V starting materials in WO 97/17084 with the annexin conjugates of Thorpe *et al.* (see column 44, lines).

Tait *et al.* teach annexin V protein conjugates, or modified annexin V protein, that are effective as an antithrombotic (see column 8; recombinant annexin V conjugates are taught in columns 9 and 10; regarding claims 1-7, 39 and 41). Tait *et al.* teach the use of the annexin V protein conjugates in methods for treating disorders resulting from thrombosis (see column 4, lines 37-41; regarding claims 8-13).

Stamatoyannopoulos teaches that in sickle cell anemia, sickled erythrocytes leads to thrombosis during the crisis stage of the disease.

Bertling *et al.* teach the use of Annexin V treatment of sickle cell anaemia (see abstract).

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It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use annexin V/antibody conjugates for the treatment of thrombosis associated with sickle cell anemia. Thorpe *et al.* and Tait *et al.* teach the use of Annexin V and Annexin V conjugates for the treatment of thrombosis, which also suggests its use for the treatment of sickle cell anemia. The person of ordinary skill in the art would have expected success as annexin V conjugates are successfully used for the treatment of thrombosis, and Annexin V has been used for the treatment of sickle-cell anemia. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

7. Claims 1, 2, and 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasina *et al.* in view of Tait *et al.* (US 5,632,986), Stamatoyannopoulos (US 4,965,251), and Bertling *et al.* (DE 195 41 284 A1).

Kasina *et al.* teach that annexins, e.g. annexin V, naturally forms multimers, and specifically dimmers, indicating that annexin V inherently couples (see column 12, line 44). Kasina *et al.* teach annexin conjugate for use as an antithrombotic (see column 10-11; regarding claims 7 and 25). SEQ ID NO: 3 is the amino acid sequence of annexin V. Kasina *et al.* does not teach the use of annexin dimmers in the treatment of sickle cell anemia.

Tait *et al.* teach annexin V protein conjugates, or modified annexin V protein, that are effective as an antithrombotic (see column 8; recombinant annexin V conjugates are taught in columns 9 and 10; regarding claims 1-7, 39 and 41). Tait *et al.* teach the use of the annexin V

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protein conjugates in methods for treating disorders resulting from thrombosis (see column 4, lines 37-41; regarding claims 8-13).

Stamatoyannopoulos teaches that in sickle cell anemia, sickled erythrocytes leads to thrombosis during the crisis stage of the disease.

Bertling *et al.* teach the use of Annexin V treatment of sickle cell anaemia (see abstract).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use annexin V dimers for the treatment of thrombosis associated with sickle cell anemia. The prior art teaches the use of Annexin V and Annexin V conjugates/multimers for the treatment of thrombosis, which also suggests its use for the treatment of sickle cell anemia. The person of ordinary skill in the art would have expected success as annexin V dimers are successfully used for the treatment of thrombosis, and Annexin V has been used for the treatment of sickle-cell anemia. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

### ***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for

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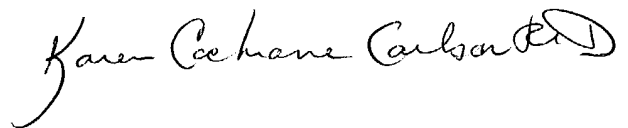
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regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS  
March 18, 2004

SKS

A handwritten signature in cursive script that reads "Karen Cochrane Carlson". The signature is written in black ink and includes a stylized "D" at the end.

KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER